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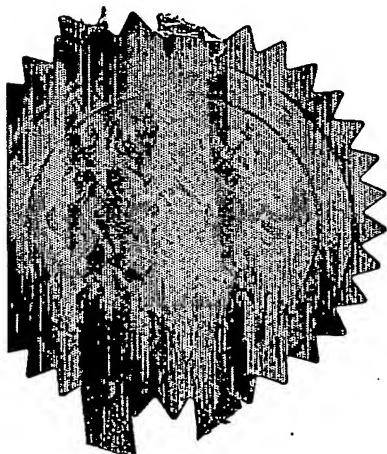
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The Patent Office

18 MAR 2003

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1. Your reference

P3881:A1 /TIPD

2. Patent application number
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0306127.2

18 MAR 2003

3. Full name, address and postcode of the or of each applicant (underline all surnames)

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Patents ADP number (if you know it)

If the applicant is a corporate body, give the country/state of its incorporation

United Kingdom

131

4. Title of the invention

Method and Device

5. Name of your agent (if you have one)

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MR GEORGE MC GOWAN
EUROPEAN PATENT ATTORNEY

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Country

Priority application number
(if you know it)Date of filing
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Number of earlier application

Date of filing
(day / month / year)8. Is a statement of inventorship and of right to grant of a patent required in support of this request? (Answer 'Yes' if:
a) any applicant named in part 3 is not an inventor, or
b) there is an inventor who is not named as an applicant, or
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Description: 12

Claim(s)

Abstract

Drawing(s)

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Priority documents

Translation of priority documents

Statement of inventorship and right to grant of a patent (Patents Form 7/77)

Request for preliminary examination and search (Patents Form 9/77)

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I/We request the grant of a patent on the basis of this application.

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TITLE: METHOD AND DEVICE

The present invention relates to a method and device,
notably to a method for monitoring a medical condition of
5 a mammal and a device for carrying out that method.

BACKGROUND TO THE INVENTION:

In order to detect or monitor a medical condition in a
10 human being or other mammal, it is often necessary to draw
a sample of the blood of the mammal and to subject that to
one or more tests to identify an illness or condition from
which the mammal is suffering or to monitor the progress
or that condition, for example its response to treatment.
15 Many of such conditions also evidence themselves by way of
the presence or absence of constituents in the urine or
other bodily fluid excreted by the mammal so that
collection of a sample of the bodily fluid and analysis or
testing of that fluid can also be used to identify or
20 monitor the condition. However, such methods are invasive
in the case of taking blood samples or require collection
of a sample of the excreted bodily fluid, which is
cumbersome and often overlooked by the patient.

25 We have now devised a method for detecting or monitoring a
medical condition in a mammal which reduces the above
problems and provides simple and effective monitoring or
detecting which is non-invasive and does not require
conscious effort by the patient.

SUMMARY OF THE INVENTION:

- Accordingly, the present invention provides a non-invasive method for detecting or monitoring a medical condition in 5 a mammal, which method comprises detecting a visual and/or colour change in a marker ingredient which interacts with one or more components of a bodily fluid excreted by the mammal to generate a colour or other visible indication which interaction is characteristic of a medical condition 10 in the mammal, characterised in that the marker ingredient is carried by a carrier member worn by the mammal and which receives at least part of the bodily fluid excreted by the mammal.
- 15 The invention also provides a device for use in the method of the invention, which device comprises a member adapted to be worn upon the body of a mammal and to receive at least some of the bodily fluid to be assessed, characterised in that the member carries one or more 20 marker ingredients which interact with one or more components of the bodily fluid to generate a colour or other visible indication which interaction is characteristic of a medical condition in the mammal.
- 25 The invention can be applied to detecting and/or monitoring a wide range of medical conditions in a range of mammals, for example kidney disorders in domestic animals, cattle or horses. However, the invention is of especial application in the monitoring and/or detection of 30 medical conditions in humans, including the excretion of

drug residues or metabolites and for convenience will hereinafter be described in terms of this preferred application.

- 5 The invention can be applied to the monitoring of an existing condition by detecting fluctuations in the interaction between the bodily fluid and a known level of marker ingredients on the carrier member. Alternatively,
10 patients to detect an infection of malfunction of an organ. It is particularly preferred that the body fluid which is contacted with the marker ingredient be urine, but the fluid may be any other which can be conveniently collected by the carrier member and for which a marker
15 ingredient gives a visible interaction which can be related to the existence or severity of a condition in the patient. For convenience, the invention will be described hereinafter in terms of testing the urine of a patient.
- 20 The invention is of especial benefit where other invasive techniques or there is patient resistance to the use of conventional non-invasive techniques. For example, the invention can be used with babies, infants, the aged or inform where the collection of clean urine samples is difficult or where the patient readily overlooks or fails
25 to carry out a routine testing programme. By collecting the urine and testing that, once the patient is persuaded to wear the carrier member, testing of the urine is inherent at each urination.

The invention can be applied to the detection of a wide range of components of the excreted bodily fluid which are indicators or medical conditions in humans. Thus, the invention can be applied to detecting sugars and sugar levels in the urine of a patient undergoing treatment for diabetes, to detecting urea, white blood cells or other indicators of infections and/or failure of the kidney or liver, cancer tumour markers, or blood in the urine. Marker ingredients for monitoring or detecting such and other conditions are commercially available and may be used in their commercially available forms in the present invention. The marker ingredients may be ones which interact directly with a component of the urine, for example in the detection of white blood cells or blood in the urine. Alternatively, the marker ingredient may be a combination of materials in which one ingredient interacts with a component of the urine to form an intermediate material which then interacts with another marker ingredient to generate the colour or visual change. An example of the latter is the interaction of glucose in the blood with glucose oxidase in the carrier member to form hydrogen peroxide which then reacts with toluidine to form a characteristic blue colour. For convenience, the invention will be described hereinafter in terms of the use of a mixture of glucose oxidase and toluidine to detect glucose in the urine.

The marker ingredient(s) are applied to the carrier medium in any suitable form so that collection of the urine from the patient brings the urine into contact with the marker

ingredients. Thus, the carrier member may be a sheet of a suitable polymer, for example the other polyethylene sheet layer of a composite diaper or incontinence pad structure, having the marker ingredient(s) applied thereto in a
5 suitable binder composition. Alternatively, the marker ingredient(s) may be absorbed into the body of the absorbent pad of such a diaper or incontinence pad. For example, the marker ingredient(s) may be applied to a component of the pad during construction of the pad using
10 conventional powder deposition techniques as are used to apply particulate super absorber materials to enhance the fluid uptake of the pad. If desired, the marker ingredient(s) may be applied in separate stages so that the initial interaction of the glucose in the urine takes
15 place at the outer layer or layers of the diaper and the resultant hydrogen peroxide then migrates into the body of the pad to interact with the toluidine within the body of the pad. However, for ease of detection of the colour or visual change in the marker ingredient(s), it is preferred
20 to apply these as a continuous or discontinuous layer or coating to an outer or external component of the pad structure. It is particularly preferred to apply the active marker ingredients in a liquid carrier containing a resinous binder to the inner or outer face of the next-to-
25 the-skin water permeable layer of the composite pad or diaper structure.

The diaper or pad typically will comprise a single or multi-layer pad of fibrillated cellulosic fibres sandwiched
30 between an inner, next-to-the-skin, water permeable layer

and an outer water impermeable layer. Such forms of construction are widely used in the manufacture of disposable diapers, sanitary pads or incontinence pads and it is particularly preferred to apply the marker 5 ingredient(s) to the inner face of the water permeable sheet forming part of the next-to-the-skin layer of the diaper by roller or other applicators. It is particularly preferred to apply the marker ingredient(s) as a series of overlapping or discrete droplets using an ink jet printer.

10

As indicated above, the carrier member is preferably one of the layers of a composite absorbent pad diaper or incontinence pad which are to be worn by the patient, for example as a diaper, trainer pant or as an incontinence 15 pad in a pair of water proof drawers or underpants. However, the invention can also be applied to other articles which are to be worn by the person, for example a colostomy or external urine collection bag. In such cases the bag is not in the form of an article of clothing as 20 with a diaper, but is carried by the person and has the urine directly excreted into it. The term worn by the patient is therefore to be construed herein as including carrier members which are attached to the person and into 25 or onto which the urine from the wearer is directly excreted and retained.

The marker ingredient(s) will usually be applied as a coating to part or all of that area of the carrier which is to receive the urine excreted from the patient. 30 However, it is within the scope of the present invention

for the carrier member to be a membrane or pad over or through which the urine flows to the main receptacle which retains the urine. For example, the marker ingredient(s) can be applied to the inner face of the tube feeding the
5 urine to the colostomy bag or can be impregnated into a pad within such a tube or in the neck of the colostomy bag.

For convenience, the invention will be described
10 hereinafter in terms of a coating of the marker ingredient(s) on the water permeable layer of the diaper or pad.

As indicated above, the marker ingredient(s) are
15 preferably applied to the water permeable layer using a roller or other conventional fluid application technique. It is particularly preferred to apply the marker ingredient(s) in a liquid carrier, for example an aqueous or solvent carrier, using an ink jet printer, for example
20 using the on-line technique described in our European Patent No 0211524B. The use of an ink jet printer technique allows the marker ingredient(s) to be deposited on the carrier member in any suitable pattern and at application rates which may vary across the surface of the
25 carrier member.

The amount and type of marker ingredient(s) which are applied to the surface of the carrier member will depend upon the nature of the marker ingredient(s), the component
30 of the urine which is being monitored or detected and may

be readily determined by simple trial and error tests. If desired, the marker ingredient(s) may be deposited and a series of layers of different ingredients and the amount of marker ingredient(s) applied may vary over the surface
5 of the carrier member to achieve different concentrations across the surface of the carrier medium.

In addition to the marker ingredient(s) the material applied to the carrier member may contain other
10 ingredients to enhance the utility of the coating or layer applied to the carrier medium. For example, the material may contain one or more colour filter materials to screen out or reduce the effect of extraneous other ingredients. Thus, the material can incorporate a red colour filter
15 medium so as to reduce the effect of blood in the urine during menstrual cycles on the blue colour generated when testing for glucose in the urine. The material applied to the carrier member may contain one or more slow or delayed release materials which progressively dissolve or break
20 down so as to permit progressive access of the urine to the marker ingredient(s). In this way the blue colour for glucose in the urine can be generated by successive excretions of urine onto the carrier member and not just by the first excretion.

25

The invention thus provides a simple and effective means by which the presence of components in the urine of a patient can be monitored without the need for invasive blood sampling and which is inherently carried out at each
30 urination by the patient without the need for the patient

to remember to take any specific action.

DESCRIPTION OF THE DRAWINGS:

5 The invention will now be described by way of illustration
with respect to a preferred embodiment thereof as shown in
the accompanying drawings in which Figure 1 is a
diagrammatic cross section through the absorbent pad of a
disposable diaper or incontinence pad to be worn in the
10 crotch area of a patient and to receive and contain urine
excreted from the patient; and Figure 2 is a cross section
through the mouth of a colostomy bag incorporating a pad
of foamed plastic or other material impregnated with a
marker ingredient and through which the urine must
15 percolate on its travel from the patient to the interior
of the colostomy bag.

DESCRIPTION OF THE PREFERRED EMBODIMENT:

20 The absorbent pad of a diaper or incontinence pad
comprised a pad 1 of fibrilated cellulose fibres or other
fibrous mass sandwiched between an outer water impervious
polythene sheet layer 2 and a water pervious next-to-the-
skin woven material layer 3. Many forms of such structure
25 are known and used in the diaper or incontinence fields
and are suitable for present use. A coating 4 of glucose
oxidase and tolidine in a polyacrylic binder is applied to
part or all of the layer 3 in the crotch region of the
pad. The coating may be continuous or discontinuous and
30 is preferably applied as an aqueous solution on line using

an ink jet printer as the sheet of woven material 3 is fed to the process during which the composite fabric of the pad is formed during the manufacture of the diaper or incontinence pad. If desired, the coating can be dried 5 using a hot air flow as the sheet 3 is fed into the diaper manufacture production process. Alternatively, the coating can be applied during production of sheet 3 prior to its subsequent transport to and use in the manufacture of the diaper.

10

In use, the pad is worn upon the crotch area of a patient and acts to receive and retain urine and faeces excreted by the patient. As the urine is excreted onto the layer 3 of the pad, any glucose in the urine reacts with the 15 glucose oxidase in the coating 4 to release hydrogen peroxide which then reacts with the toluidine in the coating to generate a characteristic blue colouration. The patient or a nurse or other carer for the patient can then readily observe that this colour has been generated 20 when the diaper or pad is removed from the patient. Where the coating contains the marker ingredient(s) incorporated into a slow release composition, this can be selected so that only some of the marker ingredient(s)n are accessible initially by the urine and further marker ingredient(s) 25 only become accessible at a later time. In this way, colour is developed initially in one area of the diaper or pad and subsequently in other areas enabling the user to determine the colour generation over a period of time and over more than one urine excretion.

30

If desired, the coating 4 can be formed on the inner face of the outer layer 2 in addition to or in replacement for the coating on layer 3 so that the generation of the blue colour can be observed through layer 2 without the need to
5 remove the diaper or pad from the patient.

In the embodiment shown in Figure 2, a patient wears a colostomy bag 10 connected by a tube 11 to his partially sectioned colon and excretes urine through tube 11 into
10 bag 10. The neck 12 of the bag 10 is fitted with a foamed plastic or other porous or foraminous plug 13 which has been impregnated with the mixture of glucose oxidase and tolidine. As the patient urinates, the glucose in the urine passing through plug 13 causes the generation of the
15 characteristic blue colour.

The generation of the blue colour in coating 4 or plug 13 alerts the patient or a nurse caring for the patient that he has glucose in his urine so that remedial action can be
20 taken. Alternatively, where the patient is known to have glucose in his urine, for example due to diabetes, generation of a blue colour would be expected. However, a change in the hue of the colour indicates a change in the level of the glucose and hence a change in the patient's
25 diabetic condition.

From another aspect, the invention thus provides a method for producing a carrier medium intended to be worn on a patient, which method comprises applying to that medium one
30 or more marker ingredients which are to interact with a

component in a bodily fluid which is excreted by the patient so as to generate a characteristic colour or other visible change.

- 5 The invention yet further provides a carrier medium to be worn upon the body of a mammal and having applied thereto one or more marker ingredients which are to interact with a component in a bodily fluid which is excreted by a mammal so as to generate a characteristic colour or other
10 visible change.

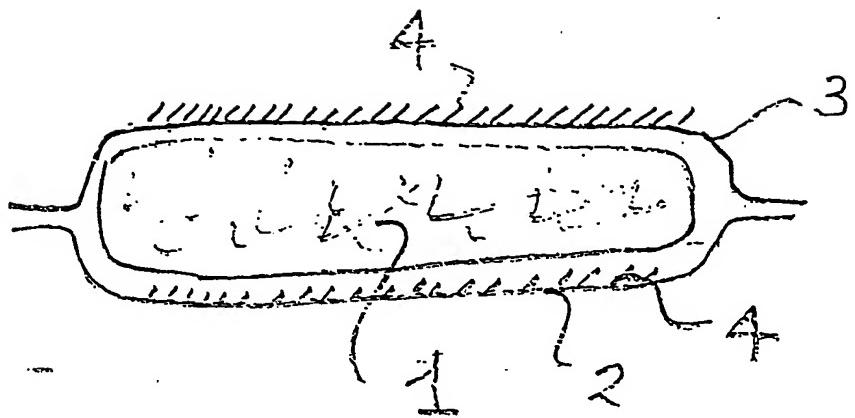


FIGURE 1

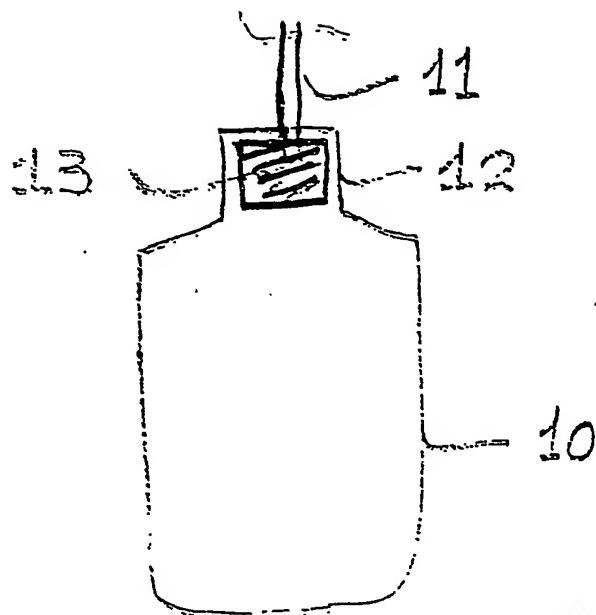


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